pending. Claim 26 has been cancelled, but the subject matter therein has been incorporated into claim 5 and new claims 28-29 and 31. It is believed that no new matter has been added. Support for the limitation "stimulating sphingolipid synthesis" can be found on page 6, lines 1-3. Support for the limitation ceramides 1, 2 and 3" as used in claim 29 can be found on page 5, fourth paragraph.

For simplicity, the rejections have been addressed with the claim numbers which were before the examiner at the time the final rejection was written. However, the applicants' also believe that their response would also apply if the previous rejections were applied to claims 5-12 and 27-31 now pending.

The applicants' extend their appreciation to the examiner for telephoning the applicants' representative to verify acknowledgement of grant of petition to withdraw the finality of the previous office action.

#### Information Disclosure Statement

It appears that there is some confusion as to the nature of the references which are listed as being considered by the examiner. Upon further review of the application, it appears that the examiner did in fact consider the references which were cited in the international search report which was submitted in an IDS (i.e. WO 98/10739; DE 196 27 344 and the English abstract for DE 196 27 344). The IDS was signed by the examiner on 4 December 2001 (part of Paper No. 6).

However, the examiner (or other office personnel) also attached to Paper No. 6 an IDS which was for SN: 09/701,719 which lists Youngdae Kim as an inventor. This IDS is not part of the applicants invention (see also the differences in the Docket Numbers) and as such is being returned by the applicants so that this paper can be matched with the proper application. The applicants request that the examiner remove any copies of this IDS from the present file.

#### Response to 103(a) rejection

Claims 5-12 and 26 were rejected by the examiner as being obvious over PI 9303217-0 A (hereafter referred to as Kurose et al. - page numbers referred for Kurose et al. are from the English language translation provided by the examiner).

### The teachings of Kurose et al. have been mischaracterized by the examiner

The examiner stated that "The catechins provide various benefits such as skin-softening, skinmoisturizing and emolliency (page 6, paragraphs 4 and 5 and page 7, last paragraph)." However, this is

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an incorrect reading of the passages cited which are reproduced below:

Page 6, paragraphs 3-5 from Kurose et al.:

The water-soluble proteins, saccharoids (sic), amino acids, and organic acids show activity conserving of the moisture of the skin (corneum) or the hair owing to their water-storing properties and formation of a colloidal film that protects water of the skin or hair from evaporation.

The moisture-conserving property of these substances averts drying or dehydration of the skin or hair, which causes the formation of microwrinkles in the skin or hair and hardening of the skin or hair, owing to the lack of moisture in the corneum, maintaining the dynamic, brilliant and transparent aspects of the skin and hair.

The lipids, resin, essential oil and chlorophyll in maté extract present emollient activities that conserve the moisture of the skin (corneum) or hair, by means of the oily film on the surface of the skin and hair, averting the problems referred to in the just-previous item."

Page 7, last paragraph from Kurose et al.:

The maté extract extracted in heated ethyl alcohol (MTE-2) present a dark green color and may be put to general use in cosmetics where all types of activity are required, such as antioxidant, improvement of vascular flow, interception of ultraviolet rays, prevention of tyrosinase activity, astringency, anti-inflammation, skin cleansing, skin-moisture conservation, emollience, and treatment of lesions or wounds, etc., owing to its balanced chemical composition."

The examiner further states that "For topical cosmetic compositions containing 0.1-1.0 wt% catechins see page 8, last paragraph." (for the examiner's purposes, this citation should probably also extend through to page 9, line 4). However, this statement is also incorrect. The wt.% referred to by the examiner refers to wt.% of MTE extracts NOT catechins.

The examiner further states that "PI '217 (Kurose et al.) does disclose that the compositions can be provided as cosmetic product for providing moisture conservation and emolliency to skin. One of ordinary skill in the art would expect from this disclosure to obtain skin moisturization and emolliency by applying these compositions to dry skin." The MTE-1 (see page 7, paragraph 6) and MTE-2 extracts disclose skinmoisturizing effects but only for the extract as a whole, not for the specific use of catechins.

Kurose et al. does not teach the limitations present in the applicants' claims MPEP 2143.03 states that "To establish prima facle obviousness of a claimed invention, all claim · Jan-09-03

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580 (CCPA 1974)).

However, there is no indication that the respective extracts of Kurose et al. have the applicants' claimed level of catechins (for MTE-1 and MTE-2, see page 3, last two paragraphs; for MTE-3, see page 8, third paragraph). The passages referred to disclose a generic mix of "catechin groups, other flavanoids, polymerized catechins and other low molecular weight polyphenols" (20.3% for MTE-1; 37.8% for MTE-2 and 54.4% for MTE-3); as such one of ordinary skill in the art would not find these passage to be a teaching or suggestion for the applicants claimed limitation of "0.001-10% by weight of a catechin, a gallic ester of a catechin, or mixtures thereof.")

With respect to the applicants' dependent claims (especially claims 6-10 and 12), the Kurose et al. disclosure is even further removed from the applicants invention as in addition to not being directed to the claimed limitation of "0.001-10% by weight of a catechin, a gallic ester of a catechin, or mixtures thereof.", the Kurose et al. reference does not teach the further limitations represented by the applicants dependent daims.

With respect to claim 26, there is no teaching or suggestion within Kurose et al. for a strengthening of the lipid barrier or increasing the rate of synthesis of ceramide of the human skin nor is any explanation given by the examiner in her rejection.

#### Closing

For the reasons cited above, the Kurose et al. reference does not render the applicants' claimed method to be obvious.

### Response to 112, first paragraph rejection

Claim 26 was rejected by the examiner as not being described in the specification in such a way as to reasonably convey to one of ordinary skill in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The examiner maintained her rejection by stating that "After a fair review of the specification, the Examiner was unable to find any mention of strengthening the lipid barrier or increasing the synthesis rates of ceramides of human skin. There was simply no written description of this provided at all."

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Given the above statement, it is presumed that the examiner also reviewed page 5, fourth line from the bottom through page 6, line 3 of the specification which the applicants assert as support for the written description requirement for claim 26. (It is also presumed that the examiner is aware that sphingolipids are lipids containing sphingosine (e.g. ceramides, sphingomyelins, gangliosides, and cerebrosides)).

Given the relatively low standards by which an inventor is deemed to have adequately described their invention, it is still unclear what is the examiner's basis for a lack of written description for claim 26. (e.g. "drawings alone may provide a 'written description' of an invention as required by § 112", see Vas-Cath, Inc. v. Mahurkar, 19 USPQ2d 1111, 1118 (Fed. Cir. 1991); "under these circumstances, we consider the original claim in itself adequate 'written description of the claimed invention. It was equally 'written description' whether located among the original claims or in the descriptive part of the specification." see In re Gardner, 178 USPQ 149, (CCPA 1973))

#### It has previously been held that:

"To satisfy the description requirement of section 112, first paragraph, an application must contain sufficient disclosure, expressly or inherently, to make it clear to one skilled in the art that the appellant was in possession of the subject matter claimed... [A] statement of the appellant's invention [in his specification] which is as broad as appellant's broadest claims' <u>is *sufficient to meet this*</u> requirement." see In re Eickmeyer, 202 USPQ 655, 662 (CCPA 1979) -- bold, italics and underlining added by writer for emphasis.

Again, no reasons or explanations were given by the examiner as to why it is believed that the applicants have not adequately described their invention.

The examiner again is reminded that MPEP 2163, section I. A. states:

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) ("we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims."). emphasis added by applicants.

### Closing

Applicants believe that this application is in condition for allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

01:40pm

· Jan-09-03

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Early and favorable action is earnestly solicited.

Respectfully submitted,

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Reg. No. 48,104

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Attachment:

Copy of IDS for SN 09/701,719 (this was erroneously sent to us; this application's SN is

09/701,710)

# CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.111 (8 pages total) is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: 9 January 2003

- Jan-09-03

Beiersdorf 688-HCL 6713-Dr. Wi-hf

# COPY OF CLAIMS SHOWING AMENDMENTS MADE

- A method [for the treatment] selected from the group consisting of [,] treatment and/or care of dry skin [,] : increasing the synthesis rate of ceramides in human skin; stimulating sphingolipid synthesis; strengthening the lipid barrier of the human skin and combinations thereof for [in] a human in need thereof which comprises applying to the skin of the human a therapeutically effective amount of a composition comprising of 0.001-10% by weight of a catechin, a gallic ester of a catechin, or mixtures thereof, based on the total weight of the composition.
- The method [for the treatment, and/or care of dry skin according to] of Claim 5, 6. wherein the catechin or gallic ester of a catechin are selected from the group consisting of (-)-catechin, (+)-catechin, (-)-catechin gallate, (-)-gallocatechin gallate, (+)epicatechin, (-)-epicatechin, (-)-epicatechin gallate, (-)-epigallocatechin, and (-)epigallocatechin gallate.
- The method [for the treatment, and/or care of dry skin according to] of Claim 5, 7. wherein the catechin is

ог a gallic ester thereof.

The method [for the treatment, and/or care of dry skin according to] of Claim 5, 8. wherein the catechin is

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or a gallic ester thereof.

- [A] The method [for the treatment, and/or care of dry skin according to] of Claim 5, 9. wherein the catechin or gallic ester of a catechin is obtained from a plant.
- [A] The method [for the treatment, and/or care of dry skin according to] of Claim 9, 10. wherein the catechin or gallic ester of a catechin is obtained from a plant from the Theaceae plant family.
- [A] The method [for the treatment, and/or care of dry skin according to] of Claim 9, 11. wherein the catechin or gallic ester of a catechin is obtained from the plant species Camellia sinensis.
- A method [for the treatment] selected from the group consisting of [,] treatment and/or care 12. of dry skin [,] : increasing the synthesis rate of ceramides in human skin; stimulating sphingolipid synthesis; strengthening the lipid barrier of the human skin and combinations thereof for [in] a human in need thereof which comprises applying to the skin of the human a therapeutically effective amount of an extract from a plant or plant parts which comprises a catechin, a gallic ester of a catechin, or mixtures thereof.
- The method of any one of claims 5-12 wherein the method is treatment and/or care of dry skin. 27.
- The method of any one of claims 5-12 wherein the method is increasing the synthesis rate of 28. ceramides in human skin.

- The method of claim 28 wherein the ceramides are ceramides 1, 2 and 3. 29.
- The method of any one of claims 5-12 wherein the method is stimulating sphingolipid synthesis. 30.
- The method of any one of claims 5-12 wherein the method is strengthening the lipid barrier of the 31. human skin.

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not considered. Include copy of this form with next communication to applicant.



# FACSIMILE COVER SHEET

**FAX RECEIVED** 

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JAN 0 9 2003 GROUP 1600

OFFICIAL

Date:

9 January 2003

To:

Examiner Alysia Berman

US Patent and Trademark Office

Tel. 703-308-4638 Fax: 703-872-9306

Subject:

USSN 09/701,710

Our Ref.: Beiersdorf 688-HCL

From:

Howard C. Lee

Comments:

Filing of response to Office Action dated 9 October 2002, including Amendment (pgs. 1-

8), Copy of Claims Showing Amendments Made (pgs. 9-11), copy of IDS for Scrial No.

09/701,749 (erroneously sent to this office) (1 pg.)

PCO

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You should receive 13 pages including this cover sheet.

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